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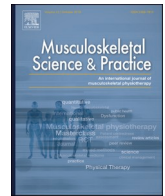
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Original article

Diagnostic ultrasound in patients with shoulder pain: An inter-examiner agreement and reliability study among Dutch physical therapists

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ABSTRACT

Study design: A cross-sectional inter-examiner agreement and reliability study among physical therapists in primary care.

Background: musculoskeletal ultrasound (MSU) is frequently used by physical therapists to improve specific diagnosis in patients with shoulder pain, especially for the diagnosis rotator cuff tendinopathy (RCT) including tears.

Objectives: To estimate the inter-examiner agreement and reliability in physical therapists using MSU for patients with shoulder pain.

Methods: Physical therapists performed diagnostic MSU in 62 patients with shoulder pain. Both physical therapists were blinded to each other's results and patients were not informed about the test results. We calculated the overall inter-examiner agreement, specific positive and negative inter-examiner agreement, and inter-examiner reliability (Cohen's Kappa's).

Results: Overall agreement for detecting RC ruptures ranged from 61.7% to 85.5% and from 43.9% to 91.4% for specific positive agreement. The specific negative agreement was lower with values ranging from 44.4% to 79.1% for RC ruptures. Overall agreement for other pathology than ruptures related to SAPS, ranged from 72.6% to 93.6% and from 77.3% to 96% for specific positive agreement. The specific negative agreement was lower with values ranging from 44.4% to 79.1% for RC ruptures and 52.5%–83.3% for other pathology than ruptures related to SAPS. Reliability values varied from substantial for any thickness ruptures to moderate for partial thickness ruptures and fair for full thickness tears. Moreover, reliability was fair for cuff tendinopathy. The reliability for AC arthritis and no pathology found was fair and moderate. There was substantial agreement for the calcifying tendinopathy.

Conclusions: Physical therapists using MSU agree on the diagnosis of cuff tendinopathy and on the presence of RCT in primary care, but agree less on the absence of pathology.

1. Background

Shoulder pain is the second most reported musculoskeletal symptom (Greving et al., 2012). A common clinical diagnosis for shoulder pain is subacromial pain syndrome (SAPS) (Diercks et al., 2014; Karel et al.,

2017). This clinical diagnosis is mainly based on history taking and physical tests (Hegedus et al., 2008; Michener et al., 2009). The term SAPS include pathologies such as: bursitis, tendinosis calcarea, supraspinatus tendinopathy, tear(s) of the rotator cuff, biceps tendinitis and tendon cuff degeneration (Diercks et al., 2014) which can be observed

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with ultrasound (Singh, 2012). We have to realize that shoulder pain cannot always be explained by pathologies in anatomical shoulder structures (Noten et al., 2017).

Recently, Musculoskeletal Ultrasound (MSU) is also considered as a useful diagnostic tool for physicians in detecting rotator cuff disorders and long head of the biceps tendon pathology (Belanger et al., 2019; Nazarian et al., 2013; Ottenheijm et al., 2010; Roy et al., 2015; Rutten et al., 2006). Reported advantages of MSU are: portability, non-invasive, cheap, lack of contraindications and quick to perform (Nazarian et al., 2013; Rutten et al., 2006). Traditionally, MSU is performed by physicians (e.g. radiologists, orthopaedic surgeons, physiatrists and rheumatologists) (Chen et al., 2011; Silva et al., 2008). The increasing technical developments, experience of operators and protocol driven approaches have improved the reliability and accuracy in finding rotator cuff pathology, in the last years (Okoroha et al., 2018; Rutten et al., 2006; Smith et al., 2011).

Nowadays, MSU is used more and more by physical therapists (PTs) to improve their specific diagnosis in patients with shoulder pain (Karel et al., 2017; Scholten-Peeters et al., 2014). However, the results of a survey showed that orthopaedic surgeons and radiologists show low trust in diagnostic MSU knowledge and skills of physical therapists and general practitioners in primary care (Scholten-Peeters et al., 2014). Primary care patients, however appreciate the use of diagnostic ultrasound performed by physiotherapists, to help them better understand their shoulder pain (Lumsden et al., 2018).

In the Netherlands 1 out of 6 physical therapy practices in primary care is now using MSU as a diagnostic tool for patients with shoulder pain and for determining the choice of physical therapy treatment (Kooijman et al., 2020). Despite the increasing use of MSU by PTs, there is a lack of studies on the reliability (and diagnostic accuracy) of PTs using diagnostic MSU in order to detect rotator cuff disorders and for determining the choice of physical therapy treatment.

One study is available showing an excellent intra-rater-reliability of MSU when performed by an experienced PT and a high intra- and interrater-reliability when performed by inexperienced PT in healthy subjects, when measuring the acromion-greater tuberosity distance (Kumar et al., 2010; Kumar et al., 2011). Another study assessed the interobserver reliability of MSU between PTs and radiologists and found an overall fair agreement and a substantial agreement for full thickness tears (Thoomes-de Graaf et al., 2014).

No studies assessed the agreement and reliability of diagnostic MSU among physical therapists in patients with shoulder pain in order to detect rotator cuff disorders in routine primary care. Therefore, the aim of this study is to assess the inter-examiner agreement and reliability in physical therapists using MSU as a diagnostic tool (detecting rotator cuff disorders) for patients with shoulder pain in primary care.

2. Methods

2.1. Study design

A cross-sectional inter-examiner agreement and reliability study. Agreement explores how outcomes of different examiners agree and is expressed in terms of observed agreement and proportion of specific agreement. Specific agreement distinguishes agreement on positive or negative outcomes. Reliability is described as how patients can be distinguished from each other, despite measurement errors (H. C. de Vet et al., 2013). The Medical Ethical Committee of the Erasmus University approved this study (number mec-2011-414). We used the 'Guidelines for reporting reliability and agreement studies (GRRAS) to report our study (Kottner et al., 2011).

2.2. Participants

Over a period of 12 months, consecutive patients with shoulder pain were recruited from different physical therapy practices in the

Netherlands. Inclusion criteria were: age over 18 years and adequate understanding of the Dutch language. All patients met the test cluster for SAPS described by Michener (Michener et al., 2009). Patients with pathologies such as cancer, infections or fractures were excluded. Post-operative patients and patients who had received any diagnostic imaging of the shoulder in the past 3 months were also excluded from this study as this could affect blinding. The included patients had not previously visited a PT who participated in this study. All patients signed an informed consent prior to the ultrasound examinations of their shoulder.

2.3. Examiners

All MSU examinations were performed by four PTs (3 male and 1 female) with more than 5 years of experience in primary care and at least 2-years MSU experience (mean 3.75 years/SD 0.47) evaluating more than 150 diagnostic ultrasound scans of the shoulder in primary care (Mullaney, 2019). All four PTs had a certificate of 'basic MSU skills' and 'MSU of the shoulder masterclass'. In addition, the participating PTs were all holding a MSc-degree in manual therapy.

In addition, all 4 PTs attended a 6 h-training meeting by a musculoskeletal ultrasound expert about the scanning protocol of the shoulder from the European Society of Musculoskeletal Radiology (Ian Beggs et al. (2016)) and discussed the relevant anatomy, pathology, scanning technique and pitfalls.

The scanning protocol consisted of 9 structures to examine in a standardized sequence (1) Long Head Biceps Tendon (LHB) (2) Subscapularis Tendon (SSC) (3) Anterior structures and Coraco-Acromial Ligament (CAL) (4) the SupraSpinatus (SSP in crass position) (5) SupraSpinatus Tendon and Rotator Interval (SSP modified crass position and RI) (6) Subacromial Impingement Test (SIT) and (7) Infraspinatus Tendon and Teres minor Tendon (TmT) (8) Posterior structures glenohumeral joint and (9) the Acromioclavicular joint (AC). Each PT used their own high-end MSU equipment which they used in daily practice, either a PHILIPS ClearVue 550 (probe: L12-4), a PHILIPS CX30 (probe: L12-4) or a Philips CX50 using a L12-3 broadband linear probe with active array technology. Each transducer had a minimum frequency of 7.5 MHz and appropriate software (beamforming technology) was available.

2.4. Procedure

Patients with the clinical diagnosis of SAPS were recruited for the study in the three physical therapy practices in primary care of the four participating PTs. Colleagues PTs of our 4 participating PTs included patients in this study. These colleagues performed the screening and if red flags were absent, they performed an added history taking and physical examination (including cluster test of Michener), to include patients for this study. The colleague PT provided a written 'physical therapy diagnosis' in terms of the International Classification of Functioning (ICF) prior to MSU examination. The PTs performing the MSU examinations and patients were not blinded for the written physical therapy diagnosis. When patients agreed to participate, they were invited for an MSU assessment in the recruiting practice by one of the PTs (PT1), followed 30 min later by a second MSU examination by one of the other participating PTs (PT2-3 or 4). Each MSU examination followed the complete scanning protocol and took about 10–15 min. Both examinations were done on the same day to avoid progression bias. Each PT completed his/her own "scan finding form" directly after the ultrasound examination and the examining PTs were blinded to each other's diagnostic MSU results. Patients were not informed about the results between examinations, so that they were not able to influence the second MSU assessor.

2.5. Outcomes

MSU diagnoses were standardized in terms of different diagnostic outcome categories (Singh, 2012): (1) Tendinopathy of the rotator cuff (T) and/or biceps, (2) Calcification of the rotator cuff (C), (3) Full Thickness Tear (FTR) of the RC and/or biceps, (4) Partial Thickness Tear (PTR) of the RC and/or biceps, (5) Arthritis of the acromio-clavicular joint (ACJa) and (6) “No pathology found”. Option (6) was only chosen when all steps of the scanning protocol were technically normal scanned and pathology was absent. The PT assessors were allowed to choose more than one outcome option.

2.6. Sample size

A sample size calculation was performed by using an online calculator (<http://wnarifin.github.io>). Based on a minimal acceptable kappa of 0.3, an expected kappa of 0.7, a proportion of outcome of 0.5, alpha of 0.05, beta of 0.8 and an expected dropout rate of 10%, we needed to include at least 50 patients in this inter-examiner study.

2.7. Statistical analysis

Descriptive analyses were conducted to describe the prevalence of positive findings and the frequencies of particular diagnostic outcome categories for each of the 9 structures. For statistical analysis, the outcome categories FTR and PTR were also grouped together as any thickness rupture. Agreement is calculated by percentage agreement (AO), Specific positive- (SPA) and Specific negative agreement (SNA). The specific positive and negative agreement, is calculated according to de Vet et al. (2013) and de Vet et al., (2018) (H. C. de Vet et al., 2013; H. C. W. de Vet et al., 2018).

Reliability is presented by a Cohen's kappa-value (k) with 95% Confidence Interval (CI) for the outcomes. The Cohen's kappa value is an agreement measure that corrects for chance and was interpreted in accordance with Landis (1977): <0.00: poor agreement, 0.00–0.20 slight agreement, 0.21–0.40, fair agreement; 0.41–0.60, moderate agreement; 0.61–0.80, substantial agreement; 0.81–1.00, almost perfect agreement. A kappa of ≥ 0.7 was considered acceptable (Landis and Koch, 1977).

The prevalence index (PI), bias index (BI) was calculated, in order to evaluate whether kappa was influenced by a high prevalence of positive or negative decisions, or by systematic bias between examiners (de Vet et al., 2013). PI reflects the absolute difference between the proportion of agreement on positive indications as compared to that of negative indications. PI ranges between 0 and 1, and is high when the prevalence of concordant positive (or negative) indications is high, chance agreement is consequently also high, and kappa is reduced accordingly (Feinstein and Cicchetti, 1990). BI provides a quantification of the extent to which raters disagree on the proportions of positive (or negative) indications. BI also ranges between 0 and 1, and is high when the absolute difference between the discordant indications is high, chance agreement is consequently low, and kappa is inflated accordingly (Feinstein et al., 1990). The hsls.pitt.edu website was used to calculate the BI and PI (Sim and Wright, 2005). The statistical analyses were performed using SPSS version 25.0 for Windows and graph-pad software (<http://www.graphpad.com>).

3. Results

We finally included a total of 62 patients, with a mean age of 54.4 years (SD 15.4) of which 36 was female and 26 was male. All patients had unilateral shoulder pain for more than 6 weeks. In 40 of the 62 cases the right shoulder was affected.

3.1. Agreement for detecting rotator cuff tears

In all cases where ruptures were seen by the MSU-assessor the supraspinatus tendon was involved. The overall agreement for detecting rotator cuff ruptures was high and ranged from 61.7% for partial thickness cuff ruptures to 85.5% for any thickness ruptures (partial and full thickness cuff tears). The specific positive agreement was also high and ranged from 87.5% for partial thickness cuff ruptures to 91.4% for full thickness cuff ruptures. The specific negative agreement ranged from 44.4% for full thickness cuff ruptures to 79.1% for any thickness cuff ruptures (Table 1a).

3.2. Reliability for detecting rotator cuff tears

The kappa value was substantial (0.68) for any thickness ruptures, slight for partial thickness cuff ruptures group (0.15) and fair for full thickness ruptures (0.35) (Table 1a).

3.3. Prevalence index and bias index for detecting rotator cuff tears

The prevalence index for detecting cuff ruptures was high and ranged from 0.31 for any thickness ruptures to 0.71 for full thickness ruptures. The bias index for detecting cuff ruptures was low and ranged from 0.00 for full thickness ruptures to 0.13 for partial thickness ruptures (Table 1a).

3.4. Agreement for detecting other shoulder pathology

The overall agreement for detecting pathology other than rotator cuff ruptures was high and ranged from 72.6% for cuff tendinopathy to 93.6% for calcifying tendinopathy. The specific positive agreement was also high and ranged from 77.3% for cuff tendinopathy to 96% for calcifying tendinopathy. The specific negative agreement ranged from 52.6% for ‘no pathology found’ to 89.8% for ACJ arthritis (Table 1b).

3.5. Reliability for detecting other shoulder pathology

The kappa value was moderate for cuff tendinopathy (0.43), ACJ arthritis (0.54) and no pathology found (0.44). There was substantial agreement for calcifying tendinopathy (0.80) (Table 1b).

3.6. Prevalence index and bias index for detecting other shoulder pathology

The prevalence index ranged from 0.21 for cuff tendinopathy to 0.69 for no pathology found. The bias index was low and ranged from 0.03 for any ACJ arthritis to 0.06 for calcifying tendinopathy (Table 1b).

Table 1a
Diagnostic category (n = 62) For detecting rotator cuff ruptures.

	PTR	FTR	ATR
Frequency			
PT 1	14	9	19
PT 2–3 or 4	9	9	24
Both	9	6	16
OA	61.7	83.9	85.5
SPA	43.9	91.4	88.8
SNA	0.78	44.4	79.1
PI	0.35	0.71	0.31
BI	0.08	0.00	0.08
Cohen's	0.15	0.35	0.68
Kappa	(0.02–0.30)	(0.03–0.69)	(0.49–0.87)

Prevalence, Cohen's kappa, overall kappa, percentage (%) of observed agreement (OA), % Specific Positive Agreement (SPA), % Specific Negative Agreement (SNA), Prevalence Index (PI), Bias Index (BI) of Full Thickness Rupture (FTR), Partial Thickness Rupture (PTR), Any Thickness Rupture (ATR), Physical Therapist (PT1), Physical Therapist 2–3 or 4 (PT 2–3 or 4)

Table 1bDiagnostic category ($n = 62$) For detecting other pathology causing SAPS.

		RC Tendinopathy (T)	RC Calcification (C)	ACJ Arthritis (ACJa)	No Pathology Found	Overall
Frequency	PT 1	23	10	12	11	
	PT 2–3 or 4	26	14	14	8	
	Both	16	10	8	5	
OA		72.6%	93.6%	83.9%	85.5%	85.5%
SPA		77.3%	96%	89.8%	91.4%	91.4%
SNA		65.3%	83.3%	61.5%	52.6%	52.6%
PI		0.21	0.61	0.58	0.69	0.69
BI		0.05	0.06	0.03	0.05	0.05
Cohen's Kappa		0.43 (0.20–0.66)	0.80 (0.60–0.99)	0.54 (0.25–0.87)	0.44 (0.14–0.68)	0.44 (0.14–0.68)

Prevalence, Cohen's kappa, overall kappa, percentage (%) of observed agreement (OA), % Specific Positive Agreement (SPA), % Specific Negative Agreement (SNA), Prevalence Index (PI), Bias Index (BI) of RC Tendinopathy, RC calcification, AC Arthritis and No Pathology Found. Physical Therapist (PT1), Physical Therapist 2–3 or 4 (PT 2–3 or 4).

4. Discussion

We found high overall agreement as well as high specific positive agreement for detecting rotator cuff ruptures and other pathology causing SAPS. For both, the overall agreement and the positive agreement was higher than the specific negative agreement. Physical therapists specialized in MSU agree more on the presence of rotator cuff tears and other pathology causing SAPS by using ultrasound than on the absence of pathology.

To the best of our knowledge this is the first inter-examiner agreement and reliability study between physical therapists performing diagnostic ultrasound in symptomatic shoulders in primary care. There is one inter-examiner study of US between PTs and radiologists which showed substantial agreement for full thickness tears, moderate agreement for bursitis and fair agreement for calcifying cuff tendinopathy in patients with shoulder pain (Thoomes-de Graaf et al., 2014). Differences between these results and ours can be explained by differences in profession who performed the MSU, differences in equipment, and MSU experience, as well as a difference in study population with Thoomes-de Graaf's group of patients being older compared to our study. In older patients, pathology might be found more frequently than in younger patients (Schmidt et al., 2015).

The kappa value for cuff ruptures varied from fair to moderate agreement and from moderate to substantial for other pathology causing SAPS. Remarkably, our study found a higher kappa value for PTR than for FTR. This is contrary to other studies (Rutten et al., 2006; Nazarian et al., 2013). Two of these studies were done among musculoskeletal radiologists in hospital care and showed excellent agreement on full thickness rotator cuff tears and good agreement for partial thickness rotator cuff tears (Rutten et al., 2010). A possible explanation for this difference may be that patients referred by an orthopaedic surgeon to hospital-based musculoskeletal radiologists already have a higher incidence of rotator cuff tears and have compared with patients in primary care. Furthermore, the MSU skill and experience of physical therapists and dedicated musculoskeletal radiologists is bound to be different. Another explanation for our reduced kappa values may be that we observed higher levels of positive agreement and lower levels of negative agreement resulting in a high prevalence index combined with a low bias index. In these situations, percentages of agreement are deemed more relevant than kappa values (H. C. de Vet et al., 2013).

The scanning protocol focused on anatomy, scan techniques and pitfalls. Although adherence to the protocol may have increased reliability, this was not determined. Some patients were not able to maintain the required position throughout both assessments because of increasing shoulder pain. Although the scanning sequence and reporting was standardized, examination presets (depth, gain, focus, frequency) were not standardized because these are operator and equipment dependent. Although all examining PTs followed a 6-h training on the study MSU protocol, not all specific diagnostic criteria for the various pathologies were discussed as mentioned in the “scan finding sheet”. This may have resulted in differences in interpretation and may have

negatively influenced the level of inter-examiner agreement but has increased the representativeness in clinical practice. Most discussion during the training session was about differences in a full thickness tear and a partial thickness tear of the RC and between a partial thickness tear and a tendinopathy of the RC. However, the differences in equipment and possibly imaging quality as well as the lack of standardized diagnostic ultrasound criteria are both reflective of the current practice of MSU by PTs in primary care. Another limitation of this study is that the both MSU examinations by a selected group of well-trained PTs were not compared with any other imaging modality or MSU by musculoskeletal radiologists. Results from this study may therefore not be readily generalized to all MSU of the shoulder in primary care, either by PTs nor by other professional groups performing MSU, let alone radiologists. The results of this small study need to be confirmed by further research. Validity of diagnostic MSU by PTs in primary care should be examined in future studies in comparison with golden standards, with MSU by dedicated radiologists and imaging modalities such as Magnetic Resonance Imaging or Computed Tomography with Arthrography. This information is needed to confirm clinical value. Furthermore, the role of the (quality of) MSU equipment as used in primary care as well as the influence of the level of training and experience of a much larger group of PTs should be assessed.

In conclusion among a limited group of physical therapists in primary care, the inter-examiner overall agreement for detecting cuff ruptures and other pathology causing SAPS is high, although reliability values are fair for partial thickness tears and slight for full thickness tears. Physical therapists specialized in MSU agree more on the presence of pathology causing SAPS than on the absence of pathology.

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Appendix A. Supplementary data

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